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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,134	03/11/2004	Gregory H. Altman	032794-054911-CIP	6963

50828 7590 12/04/2008

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
12/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/800,134	ALTMAN ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2 and 4-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 8/8/08 amended claim 1.

Claims in the application are 1, 2 and 4-49.

Claims 32-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/6/06.

Claims examined on the merits are 1, 2 and 4-31.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear as to how a fabric can be prepared containing only one yarn as required by claim 1 in line 1 reciting “one or more yarns”. A yarn is a single strand formed of fibers. If only one yarn is present, the yarn is the fabric or the converse. Given the normal definition of a fabric and a yarn, a fabric is not a yarn or the converse.

The claims are further confusing and unclear how one yarn can contain only one fiber by claim 1 in line 2 reciting “one or more sericin-extracted fibroin fibers”. If one yarn contains one fiber, the yarn is the fiber or the converse, and this is not the conventional form that is considered to be a yarn or fiber.

Claim Rejections - 35 USC § 103

Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armato et al (7,285,637), and if necessary in view of Li et al (6,303,136) and Takezawa et al (5,736,399).

The claims are drawn to a fabric comprising one or more yarns wherein the yarn comprises one or more sericin-extracted fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted, and that are biocompatible and non-randomly organized. The yarn promotes ingrowth of cells and is biodegradable.

Armato et al disclose producing non-woven silk fibroin fabrics for use as a cell culture scaffold by degumming silk fibroin to remove sericin, treating with formic acid to break disulfide bonds, and removing the formic acid by evaporation to obtain the fabric (Example 1, col 4, lines 34-50). The breaking of disulfide bonds results in chain fragments which can serve as specific cellular recognition sites promoting attachment and growth of cells (col 4, lines 21-25). Armato et al further disclose that it is known to use silk fibroin as a cell culture matrix (col 2, lines 4-17), and that textile methods would theoretically be possible to weave using merely degummed silk fibroin fibers in order to obtain a flexible fabric (col 2, lines 20-22).

Li et al disclose attaching cells to a filamentous matrix that can be made from various materials including silk (col 2, line 49 and col 4, line 18).

Takezawa et al disclose using a silk mesh as a culture carrier (col 5, lines 56-60).

It would have been obvious to omit breaking disulfide bonds as disclosed by Armato et al if the result of breaking the bonds is not desired, i.e. providing chain fragments which can serve as specific cellular recognition sites promoting attachment and growth of cells since Armato et al disclose that it is possible to merely use degummed silk fibroin fibers to obtain a flexible fabric. It is clear from Armato et al (col 2, lines 20-22) that fabric can be obtained without breaking the

bonds, and omitting breaking the bonds would have been expected to simplify the process and be an advantage. To substitute the advantage of simplification for the advantage of obtaining chain fragments having cellular recognition sites promoting attachment and growth of cells would have been within the ordinary skill of the art. Li et al disclosing attaching cells to a matrix that can be made of silk and Takezawa et al using a silk mesh as a culture carrier without a requirement for breaking bonds, if needed, would have further suggested that breaking bonds as disclosed by Armato et al can be omitted if the function of breaking bonds is not desired. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The parent application does not antedate Aromato et al since the presently claimed invention is not disclosed in the parent application.

Response to Arguments

The amendment has presented a 131 Declaration to antedate Armato et al. However, the declaration is defective in not stating that the claimed invention was made in this country, and by not being signed by all inventors. All inventors must sign a 131 Declaration unless adequate reasons can be established as to why the other inventors are unable to sign. Additionally, the evidence relied on (Exhibits A and B) do not describe an invention as presently claimed, i.e. a fabric comprising one or more yarns comprising one or more sericin-extracted fibers. The exhibits do not mention fabric and yarn. Exhibit B only discloses removing sericin from silk fibers.

The 132 Declaration filed with the amendment has not been signed, and therefore will not be considered.

The amendment urges that Armato et al does not disclose fabric containing one or more yarns. However, the use of yarn in making fabric is well known, and it would have been obvious to use a yarn containing the fibers of Armato et al in place of only the fibers to make fabric.

The amendment urges that Armato et al partially dissolve the silk fibrion with formic acid solution when breaking disulfide bonds. However, for reasons set forth above, the omission of breaking disulfide bonds would have been obvious when one does not desire the function of breaking disulfide bonds. To omit breaking the bonds merely for simplification would have been obvious. When omitting breaking the disulfide bonds, the fibers will retain their native protein structure and will not have been dissolved and reconstituted. Moreover, partially dissolving does not constitute dissolving and reconstituting since partially dissolving does not require reconstituting.

Double Patenting

Claims 1, 2 and 4-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,902,932 B2 in view of Armato et al.

The claims of the patent require a silk-fiber-based matrix composition comprising sericin-extracted silkworm fibroin fibers.

Armato et al is described as above.

It would have been obvious to provide the matrix of the claims of the patent as a fabric as suggested by Armato et al disclosing forming fabric from sericin-extracted fibroin fibers. The conditions of dependent claim would have been matters of obvious choice in view of the patent claims and Armato et al. The claims of the patent do not require dissolving and reconstituting.

Response to Arguments

This rejection has not been separately traversed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
11/22/08